

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE: NATIONAL PRESCRIPTION
OPIATE LITIGATION

This document relates to:

The County of Summit, Ohio, et al. v. Purdue
Pharma L.P., et al.
Case No. 18-op-45090

and

The County of Cuyahoga v. Purdue Pharma
L.P., et al.
Case No. 1:18-op-45004

MDL No. 2804

Hon. Judge Dan A. Polster

MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT
OF DEFENDANTS' *DAUBERT* MOTION TO EXCLUDE THE
OPINIONS OFFERED BY JONATHAN GRUBER

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INTRODUCTION

Defendants move under Federal Rules of Evidence 702 and 403, and *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579 (1993), and its progeny, to exclude Plaintiffs’ proposed healthcare economics expert Jonathan Gruber from offering expert testimony regarding causation and damages.

Gruber is a near-classic example of an expert who offers *ipse dixit* “opinions” based on no analysis whatever, instead constructing graphs and charts to “support” his opinion from an array of cherry-picked data. Indeed, Gruber goes so far as to *exclude* from his presentation data that relate to the two plaintiff counties. But graphs and charts of underlying data, which visually imply a conclusion, cannot substitute for analysis based on an accepted methodology. Legitimate expert opinion – particularly in his field – requires more than just “eyeballing” a graph.

At his deposition, Gruber could not name or point to any textbook explaining any legitimate, recognized methodology behind the graphic analyses he performed. Without any underlying reliable analysis, Gruber’s opinions illustrated through graphs and charts are not helpful to a fact finder; rather, they are misleading.

For example, Gruber purports graphically to display that Opioid Use Disorder (OUD) rates are higher in the top-quartile of states receiving prescription opioid shipments than they are in the lowest-quartile of states (Figure 1.17), hoping the fact finder will conclude, as he himself asserts, that it is the increased shipments that *cause* the higher rate of OUD. But he has no regression or other accepted analysis that attempts to prove that causal relationship. He wants the visual impression conveyed by the chart alone to carry that weight. Similarly, he purports graphically to display that opioid mortality is higher in the top-quartile of counties for shipments than in the lowest-quartile counties (Figure 1.18), again hoping the fact finder will conclude, as he himself asserts, that it is the increased shipments that cause the higher rate of mortality. But he performs

no regression or other accepted analysis that attempts to prove that causal relationship.¹ Notably, he also concedes that Cuyahoga and Summit Counties are in neither the top- nor the lowest-quartile for shipments, and thus are not reflected in his charts. Without valid underlying analyses, and without any tie to the Plaintiff counties, all of Gruber's key graphics (particularly Figures 1.16-1.20, 1.24-1.25) can only mislead the fact finder.

Unlike Plaintiffs' other expert in this area, who concedes that his regression analyses at most show *correlation*, Gruber claims that the effect of shipments on OUD and mortality is *causal*, based on nothing more than the physical appearance of his graphs. Indeed, Gruber concedes that his opinion is solely based on shipment data, not whether the medications shipped were ever consumed or harmed any patient in either Summit or Cuyahoga Counties. He admits he conducted no research or review of prescription activity or the actions of prescribers, and just looked at shipment numbers to conclude they were too large (based on his own criteria). As such, Gruber's opinions purporting to show causation through a series of misleading graphics are unreliable because he employed no methodology (much less a reliable one) to reach those opinions. Gruber's opinions therefore should be excluded.

ARGUMENT

Gruber candidly admits that he was not asked to create a comprehensive model or "delve into the magnitudes" of whether any Defendant's conduct had any effect on mortality or other harms in Summit and Cuyahoga Counties. Ex. 2 (Gruber Tr.) at 180:13-181:6; 185:4-9. Rather, he was instructed to use his "introductory report" to illustrate a relationship between Defendants'

¹ Gruber purports to perform a minor regression suggesting that economic and demographic differences across counties do not explain the variation in per capita shipments across counties. However, that regression is flawed, ignoring key variables, and in any event, does not address the cause of opioid mortality that he seeks to prove using his quartile analyses.

prescription opioid shipments and the Track One Counties' alleged harms. *Id.* at 180:13-181:6. To that end, through a series of broken links, Gruber contrived a causal connection without any underlying analysis. The Court should exclude Gruber's opinions and proposed testimony because they fall far short of the standard for admissible expert testimony under Rules 702 and 403.

I. GRUBER'S OPINIONS SHOULD BE EXCLUDED BECAUSE THEY ARE BASED ON NON-EXISTENT OR UNRELIABLE METHODS.

In determining the reliability of a proffered expert, courts scrutinize both the principles and methods used by the expert, and whether those principles and methods have been properly applied to the facts of the case. Fed. R. Evid. 702 Advisory Committee's Note (2000 Amendment) (internal marks omitted); *see* Fed. R. Evid. 702. "Any step that renders the analysis unreliable renders the expert's testimony inadmissible." *E.E.O.C. v. Ethan Allen, Inc.*, 259 F. Supp. 2d 625, 634 (N.D. Ohio 2003) (*citing In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 745 (3d Cir. 1994)). Courts agree that this is true whether an expert "completely changes a reliable methodology or merely misapplies that methodology." *Id.* Moreover, because "[e]xpert evidence can be both powerful and quite misleading," under Rule 403 the Court "exercises more control over experts than over lay witnesses." *Daubert*, 509 U.S. at 595 (citation omitted).

In *Bechak v. ATI Wah Chang*, this Court excluded expert opinions where the expert adopted the client's version of disputed facts; opined on causation and liability based on those facts; failed to consider other possible causes; and failed to adequately test the results. No. 4:15 CV 1692, 2017 WL 4541611, at *6 (N.D. Ohio Oct. 11, 2017). The same is true for Gruber's expert opinions here. Given his lack of analytical support, and choice of data that is national in scope or covers other counties, Gruber's methods are wholly unreliable for demonstrating causation as to Summit and Cuyahoga Counties.

A. Gruber's Opinions Are Drawn with Support Only from Illustrations of Underlying Data.

Gruber's quartile-based graphical analyses have not been subjected to peer review or publication, and are nowhere supported in any authoritative text as a reliable methodology to show causation. Gruber's report does not identify any authoritative source to demonstrate that this particular method has been accepted and reliably practiced in his field. Nor was Gruber able to identify any authoritative source supporting his method at any point during his deposition:

Q. Is there a name for the analysis that you're doing here that's reflected in this figure where you have -- you're comparing the highest quartile shipments with the lowest quartile shipments? What do you call that analysis?

A. I would call it a way to use the data to sort of transparently illustrate the causal relationship between shipments and mortality.

Q. . . . [F]or the work that Professor Cutler did, I know that's called a multivariate regression analysis. And I can go into lots and lots of textbooks, and they can talk to me about that, right. But if I want to look for a textbook that discusses . . . the analysis that you're doing on this page, this type of analysis, what do I look for in the index? What's this called?

A. I would not say this has a particular methodological name. You would see, if you looked at many, I might say most, modern empirical economic analyses, they will typically include, in addition to multivariate regression analysis, increasingly they're including graphical illustrations of the data so that the reader can -- the reader who is not -- the reader can transparently understand what's going on in the data, rather than to rely on the statistical interpretation. So we typically, you know, so we encourage our students today when they're writing a paper to include both figures that transparently illustrate the story they are trying to tell, as well as using underlying statistical analysis to make that more concrete.

Q. And I'm not focused so much on the graphic itself as the analysis that . . . underlies the graphic, where . . . you take the lowest quartile and the highest quartile, and you've shown a difference in terms of mortality, growth between those two quartiles. What's the name of that analysis so I can find it in a textbook?

A. I don't know that there's a common name for this analysis that you find in a textbook. . . .

Ex. 2 (Gruber Tr.) at 400:19-403:23.

Gruber thus concedes that his graphical quartile-based analyses (at least Figures 1.16-1.20, 1.24-1.25) are not described in or supported by any authoritative text, and are not based on any

accepted economic methodology that might prove causation. Instead, Gruber skips the analytics and simply illustrates the underlying data in a misleading way to try to convince a fact-finder to draw an unsupported causal conclusion. That is patently unacceptable expert testimony. It is misleading and not based on any reliable, tested methodology. It therefore should be excluded. *See* Fed. R. Evid. 702, 403; *Daubert*, 509 U.S. 579; *see also In re Heparin Prods. Liability Litig.*, 803 F. Supp. 2d 712, 736 (N.D. Ohio 2011) (opinion not based on reliable methodology is inadmissible to show cause).

B. Even If Gruber Had Performed an Analysis, It Would Not Have Supported a Causal Conclusion.

Gruber opines that there is “a *direct, causal relationship* between defendants’ shipments of prescription opioids and the misuse and mortality from prescription opioids, with geographic areas that received higher volumes of per capita shipments of prescription opioids experiencing significantly higher rates of opioid related misuse and mortality.” Ex. 1 (Gruber Rpt.) at 8-10, ¶16 (emphasis added). He further asserts that there is a direct causal relationship between shipments of prescription opioids and the misuse of and mortality from *illicit opioids*, which accelerated rapidly after 2010. *Id.*

Yet even Gruber has recognized that “[a] fundamental issue faced by doing empirical work in economics [is] disentangling causality from correlation.” Jonathan Gruber, PUBLIC FINANCE AND PUBLIC POLICY 66 (Worth Publishers, 2015). Gruber also understands that it is generally accepted in the field of economics that “two economic variables are correlated if they move together . . . this relationship is causal *only if* one of the variables causes the movement in the other. If, instead, there is a third factor that causes both to move together, the correlation is not causal.” *Id.* (emphasis added). He admitted at his deposition that establishing causation requires at least an underlying analysis:

Q. And do you agree that correlation should not be interpreted as a causal relationship without analysis of the underlying process generating the data?

A. Yes, I do.

Ex. 2 (Gruber Tr.) at 106:15-20.

Yet, ignoring this requirement, the graphical analyses that Gruber uses here are designed to show, at most, that several variables move together. He leaps from correlation to causation, admitting that he did so with no analytical support, only a hypothesis. *See, e.g.,* Ex. 2 (Gruber Tr.) at 168:24-169:20, 179:22-180:12:

Q. What you're illustrating in Figure 1.17, is that more accurately described as a correlation as opposed to causation?

A. This is described as an illustration of a relationship that is -- this is an illustration of a relationship that is consistent with hypothesis I lay out in the data, in the report.

Q. And while it's consistent with your hypothesis, contained within your report or the appendix, [it] is not a data analysis to prove a relationship between the two, correct?

A. That is correct.

* * *

Q. Okay. All right. So with regard to your analysis of a potential relationship between shipments and opioid mortality, did you perform a regression analysis to explore that?

A. In this report, I did not. This uses the kind of illustrative graphs and regression analysis as contained in Professor Cutler's report.

Q. Do you rely on the information contained in Professor Cutler -- Professor Cutler's report for your analysis and conclusions in this section of your report?

A. I do not rely on that, no.

Gruber's opinions therefore should be excluded for ignoring economic precepts he himself recognizes concerning what is necessary to show causation. *See Kentucky Speedway, LLC v. Nat'l Ass'n of Stock Car Auto Racing, Inc.*, 588 F.3d 908, 916 (6th Cir. 2009) (excluding expert who "used his own version" of the test, which "had not been tested, had not been subjected to peer

review, had no controlling standards, had no demonstrable showing of support within the scientific community, and was produced solely for purposes of the instant litigation”).

C. Gruber Fails To Address Specifically Cuyahoga and Summit Counties.

In his graphical analyses, Gruber measures shipments, OUD, opioid mortality, and crime across states and counties grouped into the lowest and highest quartiles. He does not measure or analyze relationships between these factors in respect of Cuyahoga and Summit Counties specifically, and provides no evidence that the same relationships would hold in those counties.

For example, Gruber’s graphical depiction of OUD compares prevalence of that disorder between a 25 percent grouping of the states with the highest prescription opioid shipments and a 25 percent grouping of states with the lowest shipments. *See* Ex. 1 (Gruber Rpt.) at 55-57, ¶¶ 79-81. He performs a similar graphical analysis for opioid mortality using the top and bottom quartiles of counties based on shipments. *Id.* at 57-61, ¶¶ 82-87. And he performs a similar quartile-based graphical analysis of crime. *Id.* at 76-80, ¶¶ 108-12. He bases each of these analyses on the difference between the top 25 percent and bottom 25 percent. The middle two quartiles are not covered by his graphics.

However, Gruber concedes that “there are wide differences across counties in the growth of per capita shipments over time.” Ex. 1 (Gruber Rpt.) at 54, ¶ 78. Gruber also acknowledges that Summit and Cuyahoga Counties do not appear in either the top or bottom quartile in terms of shipments. *See* Ex. 2 (Gruber Tr.) at 162:11-163:6; Ex. 1 (Gruber Rpt.) at 42, ¶ 64. Gruber makes no effort to show that the causal conclusions he draws from his graphical top- and bottom-quartile analyses even hold as to Cuyahoga and Summit Counties. At deposition, Gruber came to admit that Cuyahoga and Summit are not included within the county groupings depicted in his bar charts and line graphs. *See* Ex. 2 (Gruber Tr.) at 162:16-163:6, 166:1-13:

Q. Is it true that Cuyahoga County is not in the group of counties in the top 25 percent of shipments?

A. I believe that's true, yes.

Q. And is it also true that Summit County is not in the group of counties in the top 25 percent of shipments, correct?

A. I believe that's true, yes.

Q. And is it true that Cuyahoga County is not in the bottom 25 percent of counties?

A. That's correct.

Q. And same for Summit County?

A. That's correct.

* * *

Q. Okay. Do you agree that Cuyahoga and Summit Counties would not be included in the red line on Figure 1.16 for the top 25 percent shipments?

A. Yes, I agree.

Q. And you agree that they would not be included in the blue line at Figure 1.16 for the bottom 25 percent of shipments?

A. Yes, I agree.

Q. Their category is not depicted in this figure, correct?

A. That's correct.

Thus, Gruber concedes that his graphic opinions do not measure or even include effects in Cuyahoga and Summit Counties. In fact, he admits that he didn't perform an analysis or create a graph for the quartiles to which Cuyahoga and Summit Counties belong. *See id.* at 164:15-165:14. He brushes that criticism aside, however, stating that the point of his graphic opinions is to show "central tendencies" in the underlying data. Yet Gruber admits that the central tendencies do not apply to Cuyahoga and Summit, which are at least exceptions, if they do not disprove his rule. *See id.* at 432:18-434:15:

Q. Well, on page -- on Page 43, in Figure 1.10 we can see that the shipments into Summit were much higher than the shipments into Cuyahoga, right?

A. Yes.

Q. But the mortality, as reflected on Figure 1.11, is roughly the same as between the two counties. And I would have thought if shipments, in fact, are driving mortality, that the higher shipments in Summit would have led to higher mortality, but instead, the higher shipments resulted in about the same mortality. So I'm -- I'm asking if you can square that for me.

A. So two answers. One is about the same until 2014 when -- when Summit does get higher. And the second answer is, as I said before, we're trying to use these data to explain the central tendencies that both, as I say, if you do a sort of transparent graphical analysis or regression analysis, there's a clear relationship between shipments in 2010 and opioid mortality. That does not mean that that relationship -- that does not mean you cannot find an observation of data or two for which that relationship doesn't appear to hold. You can take any empirical analysis and find a pair of observations where the relationship estimated for the central tendency of the data doesn't hold for that pair of observations.

Q. And here the pair of observations is Cuyahoga and Summit, right?

A. That's correct.

Gruber surprisingly justifies his decision to ignore the two middle quartiles, which include Cuyahoga and Summit, because it allows him to show stronger conclusions. *See id.* at 191:12-23:

Q. What results would you find if you compared the second and third quartiles as opposed to the highest and lowest shipment areas with regard to addressing the measurement error?

A. I don't know for sure. But the -- once again, as I described with measurement error, if there's some measurement error, then obviously the more you really distinguish clear groups, like the top and the bottom, the -- the stronger your conclusions can be.

But that justification proves why his opinions should be excluded. Even putting aside the lack of any supporting analysis, Gruber's graphics showing "central tendencies" in the data are indisputably misleading when this case concerns two counties that are not included in those graphics.

Gruber's method of extrapolation to measure harms in Cuyahoga and Summit fails to satisfy the factors considered by courts in assessing reliability. *See Daubert*, 509 U.S. at 592-94.

First, the conditions under which Gruber compared states and counties were improper for testing on a county-by-county basis. He measures the relationship between (a) average shipment levels for large groupings of states or counties, and (b) differences in OUD or opioid-related mortality. But Gruber does not attempt to isolate the levels of excess shipments in each state or county, nor does he attempt to correlate those isolated levels with differences in OUD or mortality. Moreover, in assessing the top and bottom quartiles, Gruber does not explain (or even acknowledge) that many counties in the top quartile of shipments had below-average mortality rates, while many counties in the bottom quartile of shipments had above average mortality rates. *See* Ex. 3 (Corrected and Restated Expert Report of Certain Defendants' Expert Kevin M. Murphy, Ph.D. ("Murphy Rpt.)) at 70, ¶ 117. Gruber then presents his findings in charts that conceal the fact that many counties did not fit neatly in the "predictions" of his analysis. Thus, county- or even state-level analyses cannot be replicated, weighing against reliability.

Second, the potential error rate of Gruber's methodology is high. His measures do not reflect the actual conditions of Summit and Cuyahoga Counties. Instead, he presents a view of high- and low-shipment areas which *do not include Summit and Cuyahoga*. He then compares them to each other, despite acknowledging that there were marked differences between this comparison and real-life conditions. Further, this method suffers from additional measurement errors that Gruber mentions but does not control for. In his report, Gruber states that a "transshipment problem"—where consumption of an opioid could take place in a location different than the shipment of an opioid—induces "measurement error into [Gruber's] comparisons, reducing the power of shipments to distinguish high versus low use areas." Ex. 1 (Gruber Rpt.) at

57, ¶ 83. Yet, despite his awareness of this error, he purposefully chose to use shipments as an inaccurate proxy for opioid consumption.

D. Gruber Relies on a “Gateway” Hypothesis That Is Fundamentally Flawed.

With no analytical support, Gruber opines that “prescription opioids have become the predominant gateway to heroin use, a pattern not observed in earlier decades, and thus that the illicit opioid crisis is a direct result of defendants’ misconduct.” Ex. 1 (Gruber Rpt.) at 62, ¶89. This issue is more fully discussed in Defendants’ *Daubert* motion concerning Plaintiffs’ gateway theory. To briefly address it here, the weight of economic literature acknowledges that this proposition is flawed, and Gruber’s reliance should be rejected for lack of underlying data and reliability.

According to the academic literature, rather than observing a gateway, experts observe that heroin usage has continued to rise over recent years and is projected to soon overtake nonmedical prescription opioids as the primary initiator of opioid use. *See, e.g., Cicero et al., Increased use of heroin as an initiating opioid of abuse: Further considerations and policy implications*, 87 ADDICTED BEHAVIORS 267-69 (2018). The literature that Gruber relies on for “epidemiological support” for the gateway theory suffers from methodological limitations which renders it unreliable, as described in Defendants’ gateway motion.

Apart from relying on flawed studies, Gruber also completely ignores evidence contradicting the gateway hypothesis. For example, as certain Defendants’ expert Professor Murphy points out, even if it were true that many heroin users once abused prescription opioids, the relevant question to test the gateway hypothesis is whether most users of prescription opioids go on to abuse heroin, and they do not. *See* Ex. 3 (Murphy Rpt.) at 106, ¶ 170. Gruber in fact admitted in his deposition that the percentage of prescription opioid users who go on to abuse heroin is in the range of only 1%. *See* Ex. 2 (Gruber Tr.) at 394:20-395:20. In addition, the most

prevalent users of prescription opioids are older, while the most prevalent abusers of heroin are younger. *See* Ex. 3 (Murphy Rpt.) at 107-08, ¶¶ 172-73. Clearly, older individuals using prescription opioids are not passing through a gateway to become younger individuals abusing heroin. Gruber's gateway opinion rests on no reliable data or other evidence, and is not accepted in the field.

II. GRUBER'S OPINIONS DO NOT FIT AND ARE IRRELEVANT TO PLAINTIFFS' CLAIMS.

Gruber's opinions should be excluded for the independent reason that they do not "fit" and are irrelevant to the pertinent inquiry presented in this case: whether Defendants' alleged misconduct caused the alleged harms to Summit and Cuyahoga Counties. To be relevant, expert evidence must "assist the trier of fact to understand the evidence or to determine a fact in issue." Fed. R. Evid. 702.

Courts routinely exclude causation experts who, like Gruber, offer opinions that fail to connect the alleged misconduct to the alleged injury. For example, in *Botnick v. Zimmer, Inc.*, this Court held that, to be admitted under *Daubert*, the plaintiff's causation expert's testimony "must exhibit relevancy, **connecting his theory** of an alleged defect in the medical device to [the plaintiff's] injury." 484 F. Supp. 2d 715, 721 (N.D. Ohio 2007) (emphasis added). In excluding the expert, the Court determined that the testimony lacked that critical connection, as it was "not driven, as it must be, by the context of the issues in this case." *Id.*

Gruber does not offer causation opinions that advance Plaintiffs' theories. Plaintiffs rely on Gruber's opinions in support of their argument that Defendants' excess shipments of prescription opioids to Summit and Cuyahoga Counties caused the growth in the misuse of opioids and increases in licit and illicit opioid-related mortality over the past 20 years in Summit and Cuyahoga Counties. But Gruber never attempts to link alleged wrongdoing by any particular

Defendant, or even all of them jointly, to specific harms in Summit and Cuyahoga Counties. Instead, Gruber makes comparisons across states and counties in the top and bottom quartiles for shipments. Neither quartile, however, includes Summit and Cuyahoga Counties.

Even more egregious is the absence of any effort by Gruber to fit his opinions to a specific Defendant or to separate Defendants' conduct from that of other contributors who are not parties to this litigation. His analysis did not isolate shipments from only the Defendants in this case and looked at prescription opioid shipments as a whole, across all manufacturers and distributors and across all opioid medications. Ex. 2 (Gruber Tr.) at 56:9-23; 57:13-22; 58:3-59:1. Indeed, Gruber admits that he has not formed any opinions with respect to any specific Defendant, and has not determined cause attributable to any specific Defendant, much less tied to Cuyahoga or Summit Counties specifically. *See id.* at 51:17-53:4, 56:9-57:22, 125:4-13.

Moreover, not once does Gruber attempt to separate the impact from illicit opioids, particularly heroin and fentanyl—instead opting to attribute all opioid-related harms to the Defendants. According to Gruber, if Defendants' prescription opioid shipments caused an increase in licit opioid misuse and mortality, then those shipments must also be responsible for increases in illicit opioid misuse and mortality. This conclusion is supported by nothing other than Gruber's say-so. It is devoid of any underlying analysis, and should not be permitted in a court of law.

Further, Gruber's opinion acknowledges that forces outside of Defendants' control—namely, state drug monitoring programs, increased scrutiny by the government, state caps on prescriptions, and law enforcement actions on “pill mills” were a contributing cause of why individuals with opioid abuse disorder began moving towards use of illicit opioids like heroin, yet he concedes he has not done any work to apportion how each of those causes influenced illicit use. *See id.* at 62:21-64:16.

Gruber's opinions do not assist the trier of fact in addressing the question at issue in this litigation precisely because they lack the critical connection between alleged misconduct and alleged injury. His failure to attribute any particular harms suffered by the Track One Counties to any Defendant's alleged misconduct, not to mention any particular shipment, or any particular opioid, renders his opinions unreliable and unhelpful, and thus, inadmissible.

CONCLUSION

For the foregoing reasons, the Court should exclude Gruber's opinions and proposed testimony.

Dated: June 28, 2019

Respectfully submitted,

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CERTIFICATE OF SERVICE

I, Geoffrey E. Hobart, hereby certify that the foregoing document was served via the Court's ECF system to all counsel of record.

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